

**UNITED STATES DISTRICT COURT**

**DISTRICT OF MINNESOTA**

**MARY MALFITANO and  
VINCENT MALFITANO,**

**PLAINTIFFS,**

**V.**

**MENTOR CORPORATION,**

**DEFENDANT.**

**CIVIL ACTION NO.:**\_\_\_\_\_

## JURY DEMAND

## COMPLAINT

The Complaint and Demand for Jury Trial of Mary Malfitano and Vincent Malfitano (hereinafter collectively referred to as “Plaintiffs”) shows as follows:

## **JURISDICTION AND PARTIES**

1. At all times relevant herein, Plaintiffs were residents of the State of New Jersey.
2. At all times relevant herein, Defendant Mentor Corporation (hereinafter “Defendant” or “Defendant Mentor”) was a Minnesota corporation with its principal place of business in California. All acts and omissions of Defendant Mentor as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.
3. Plaintiffs are seeking damages in excess of \$75,000.00. Subject matter jurisdiction is proper pursuant to 28 U.S.C. Section 1332.
4. A substantial part of the events and omissions giving rise to Plaintiffs’ causes of action occurred in the Minnesota. Defendant Mentor is incorporated in Minnesota, has significant contacts in Minnesota, and has earned substantial compensation and profits from sales

of its products in this District. Pursuant to 28 U.S.C. Section 1391(a) venue is proper in the District of Minnesota.

### **FACTUAL BACKGROUND**

5. At all times relevant herein, Defendant Mentor was engaged in the business of designing, manufacturing, marketing, packaging, labeling, and selling medical devices, including a medical device known as “ObTape,” a transobturator vaginal sling implanted suburethrally to treat certain women like Plaintiff Mary Malfitano for stress urinary incontinence, and placing such devices in the stream of commerce.

6. Defendant brought the ObTape to market in the United States in 2003 without adequate pre-market testing as to the safety and efficacy of said device (the only pre-market “testing” that Defendant performed on the ObTape was animal testing – on three rabbits). Even the limited pre-market testing that Defendant did perform revealed that the ObTape caused adverse tissue reaction in rabbits. After the ObTape was brought to market, Defendant performed no additional safety or efficacy testing in human vaginal tissues regarding said device.

7. Defendant made material misrepresentations to the Federal Food and Drug Administration concerning the design, manufacture, safety, and efficacy of the ObTape vaginal sling.

8. Before Plaintiff Mary Malfitano suffered the injuries complained of herein, Defendant was on notice of numerous bodily injuries caused by the ObTape, and based thereon; Defendant knew or should have known that the ObTape caused an unreasonably high rate of vaginal erosion, infection, extrusion, perforation and/or abscess in women implanted with said device.

9. Even though Defendant knew or should have known much earlier than March of 2006 that the ObTape created a foreseeable, unreasonable risk of harm to those women who are implanted with said device, Defendant failed to stop marketing the ObTape in the United States until in or around March of 2006, and not until after Defendant had sold thousands of these devices in the United States alone, including the ObTape vaginal slings ultimately implanted in Plaintiff Mary Malfitano.

10. Even after Defendant ceased marketing the ObTape device in the United States in or around March 2006 because of the numerous injuries caused by the product, Defendant never provided adequate warning or information to physicians who implanted the device, or to women who are implanted with the device, that the ObTape caused an unreasonably high rate of vaginal erosion, infection, extrusion, perforation and/or abscess.

11. Plaintiff Mary Malfitano underwent a surgical procedure wherein she was implanted with a Mentor ObTape vaginal sling.

12. Subsequently, as a direct and proximate result of the defective condition of the Mentor ObTape vaginal sling and other misconduct of Defendant as described in this Complaint, Plaintiff Mary Malfitano suffered serious bodily injury, experienced significant mental and physical pain and suffering, have required multiple surgeries, and have sustained permanent injury and other damages.

**COUNT I – STRICT LIABILITY – DEFECTIVE MANUFACTURE**

13. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

14. Defendant is engaged in the development, testing, manufacturing, marketing and sales of Mentor ObTape vaginal slings. Defendant designed, manufactured, assembled and sold Mentor ObTape vaginal slings, knowing that they would then be implanted in patients.

15. Defendant distributed and sold the Mentor ObTape vaginal slings in the condition in which they left their place of manufacture, in their original form of manufacture, which included the defects described herein.

16. The Mentor ObTape vaginal slings were expected to and did reach Plaintiff Mary Malfitano without substantial change in the condition in which they were sold and/or distributed by Defendant.

17. Mentor ObTape vaginal slings are defectively manufactured because the foreseeable risks outweigh the benefits associated with the Mentor ObTape vaginal slings.

18. The Mentor ObTape vaginal slings were defective in manufacture and unreasonably dangerous to the user or consumer when they left the Defendant's possession or control in that it deviated materially from the Defendant's design and manufacturing specifications in such a manner as to pose an unreasonable risk of serious bodily harm to Plaintiff Mary Malfitano.

19. Certain of Defendant's design and manufacturing specifications for the ObTape product called for a minimum pore size of 50 microns in order to promote proper tissue in-growth.

20. When the ObTape slings left the Defendant's possession or control, they deviated in a material way from Defendant's design and manufacturing specifications for the ObTape product in that the pores in the ObTape sling are smaller than 50 microns, which prevented

proper integration of the vaginal sling and impaired necessary tissue in-growth, thereby increasing the likelihood of serious infection, abscesses, vaginal erosion and extrusion.

21. Defendant knew or should have known of the manufacturing defects and the risk of serious bodily injury that exceeded the benefits associated with the Mentor ObTape vaginal sling.

22. The Mentor ObTape vaginal slings presented an unreasonably dangerous risk beyond what the ordinary consumer would reasonably expect.

23. Mentor ObTape vaginal slings are inherently dangerous for their intended use due to manufacturing defect and improper functioning. Defendant is therefore strictly liable.

24. As a direct and proximate result of the defective manufacture of the Mentor ObTape vaginal sling, Plaintiff Mary Malfitano suffered serious and permanent bodily injuries, experienced significant mental and physical pain and suffering, has required multiple surgeries, and has expended and will continue to expend large sums of money for medical care and treatment, has suffered and will continue to suffer economic loss and/or lost income, and has otherwise been physically, emotionally and economically injured.

## **COUNT II – STRICT LIABILITY – DEFECTIVE DESIGN**

25. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

26. The Mentor ObTape vaginal sling designed, developed, tested, manufactured, marketed and sold or otherwise placed into the stream of commerce by Defendant is in a dangerous and defective condition and posed a threat to any user or consumer of the Mentor ObTape vaginal sling. Plaintiff Mary Malfitano is in a class of persons that Defendant should

have considered to be subject to the harm caused by the defective nature of the Mentor ObTape vaginal sling.

27. Mentor ObTape vaginal sling was implanted in and used by Plaintiff Mary Malfitano in the manner for which it was intended.

28. Defendant knew or should have known that the Mentor ObTape vaginal sling created a high risk of bodily injury and serious harm.

29. The Mentor ObTape sling was defective in design in that at the time it left Defendant Mentor's control, the foreseeable risks of harm associated with its design exceeded the benefits associated with said design.

30. The material of which the ObTape sling was constructed (non-woven, microporous, inelastic polypropylene mesh) was inappropriate for use in the vaginal area.

31. The pore size of the polypropylene mesh sling was insufficient to allow for proper physiological reaction of the body to the device, in that the pore size was too small to permit in-growth of small blood vessels, cells that make collagen, and white blood cells.

32. The inappropriate material and inadequate pore size in the Mentor ObTape vaginal sling created a propensity for infection and/or abscess when placed in the vaginal area, which consequently resulted in an unreasonably high rate of infection, abscesses, erosion and extrusion.

33. The foreseeable risks of harm posed by the design of the ObTape vaginal sling could have been reduced and/or avoided by the adoption of a reasonable alternative design by the Defendant, and Defendant's failure to adopt a safer alternative design rendered the ObTape vaginal sling unreasonably unsafe.

34. As a direct and proximate result of the defective design of the Mentor ObTape vaginal sling, Plaintiff Mary Malfitano suffered serious and permanent bodily injuries, experienced significant mental and physical pain and suffering, has required multiple surgeries, and has expended and will continue to expend large sums of money for medical care and treatment, has suffered and will continue to suffer economic loss and/or lost income, and has otherwise been physically, emotionally and economically injured.

**COUNT III – STRICT LIABILITY – FAILURE TO WARN OR INSTRUCT**

35. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

36. Defendant distributed and sold the Mentor ObTape vaginal slings in the condition in which they left their place of manufacture, in their original form of manufacture, which included the defects described herein. The Mentor ObTape vaginal slings were expected to and did reach Plaintiff Mary Malfitano without substantial change in the condition in which it was sold and/or distributed by Defendant.

37. The Mentor ObTape vaginal sling is defective due to inadequate warnings or instruction because Defendant knew or should have known that the Mentor ObTape vaginal sling created a high risk of bodily injury and serious harm. Defendant failed to adequately and timely warn consumers of this risk.

38. Defendant failed to provide such warning or instruction that a manufacturer exercising reasonable care would have provided to physicians who implanted the Mentor ObTape vaginal sling, or those women who had been implanted with an ObTape vaginal sling, concerning the following risks, of which Defendant had actual or constructive knowledge at the time the ObTape vaginal sling left Defendant's control: the high failure rate of the ObTape

product; the high rate of infections and abscesses caused by the product; the high rate of vaginal erosions and extrusions caused by the product; the ObTape's susceptibility to vaginal erosion, and the consequential necessity to remove the entire sling from the patient's body in the event of an erosion; and, that the product was unsafe for the use for which it was intended, that is treatment of female stress urinary incontinence.

39. After receiving notice of numerous bodily injuries resulting from the ObTape product after the ObTape vaginal sling left the Defendant's control, the Defendant failed to provide such post-marketing or post-sale warning or instruction that a manufacturer exercising reasonable care should have provided to physicians who implanted the ObTape vaginal sling or those women who had been implanted with the ObTape vaginal sling that the product was causing an unreasonably high rate of infections, abscesses, erosions and/or extrusions, and Defendant failed to provide such post-marketing or post-sale warning or instruction concerning the ObTape's susceptibility to erosion and the consequential necessity to remove the entire sling from the patient's body in the event of an erosion.

40. As a direct and proximate result of the Defendant's inadequate warning and instruction, both at the time of marketing and after the sale of the ObTape vaginal sling, Plaintiff Mary Malfitano suffered serious and permanent bodily injuries, experienced significant mental and physical pain and suffering, has required multiple surgeries, and has expended and will continue to expend large sums of money for medical care and treatment, has suffered and will continue to suffer economic loss and/or lost income, and has otherwise been physically, emotionally and economically injured.

**COUNT IV - NEGLIGENCE**



41. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

42. Defendant owed a duty to Plaintiff Mary Malfitano to exercise ordinary and reasonable care in designing, manufacturing, testing, marketing, labeling, packaging, selling and/or distributing the ObTape vaginal sling, and to exercise ordinary and reasonable care in providing adequate warnings and instructions to Plaintiff Mary Malfitano and to her physicians regarding the ObTape vaginal sling.

43. Defendant failed to exercise ordinary and reasonable care in designing, manufacturing, testing, marketing, labeling, packaging, selling and/or distributing the ObTape vaginal sling, and Defendant negligently failed to provide adequate warnings and instructions to Plaintiff Mary Malfitano or to her physicians regarding the ObTape vaginal sling.

44. Defendant breached their duty of reasonable care to Plaintiff Mary Malfitano by failing to promptly and adequately notify the FDA and warn, and instruct Plaintiff Mary Malfitano, the medical community, and the public at the earliest possible date of known defects in the Mentor ObTape vaginal sling.

45. Defendant breached their duty of reasonable care to Plaintiff Mary Malfitano by failing to exercise due care under the circumstances.

46. As a direct and proximate result of the Defendant's negligence, Plaintiff Mary Malfitano suffered serious and permanent bodily injuries, experienced significant mental and physical pain and suffering, has required multiple surgeries, and has expended and will continue to expend large sums of money for medical care and treatment, has suffered and will continue to suffer economic loss and/or lost income, and has otherwise been physically, emotionally and economically injured.

**COUNT V - LOSS OF CONSORTIUM CLAIM ON BEHALF OF –**  
**PLAINTIFF VINCENT MALFITANO**

47. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

48. As a direct and proximate result of the Defendant's actions as described herein, including, but not limited to, their failure to comply with federal standards and requirements, Plaintiff Vincent Malfitano has suffered the loss of his wife's services, companionship, society, and consortium, emotional distress and mental anguish, and he will continue to suffer such loss and damages in the foreseeable future.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs pray for judgment against Defendant as follows:

1. Economic and non-economic damages in an amount in excess of \$75,000 as provided by law and to be supported by the evidence at trial;
2. For compensatory damages according to proof;
3. For an award of fees and costs;
4. For prejudgment interest and the costs of suit; and
5. For such other and further relief as this Court may deem just and proper.

**DEMAND FOR JURY TRIAL**

Plaintiffs hereby demand a trial by jury as to all claims in this action.

Dated this the 7<sup>th</sup> day of December, 2009.

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